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No. .....

In The

Supreme Court of the United States

October Term, 1984

KENNETH W. KIZER, M.D., M.P.H., Director of the Department of Health Services;
GEORGE DEUKMEJIAN, Governor of the State of California;
STATE OF CALIFORNIA, a political entity,
Petitioners,

v.

ANNA JENESKI, WILLIAM SWAIN, EDITH PANTILLA, and ARTHUR COLVIN,
Respondents.

PETITION FOR WRIT OF CERTIORARI TO THE CALIFORNIA COURT OF APPEAL, SECOND APPELLATE DISTRICT

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QUESTIONS PRESENTED

1. Whether the requirements of 42 C.F.R. section 440.230(c) (1) apply to optional benefits under the Medi-Cal program.

2. Whether California's prior authorization system, as it applies to the prescription drug program, is invalid because it does not provide pre-denial hearings to beneficiaries whose requests for drugs, that are subject to the prior authorization procedures, are denied.

3. Whether California's prior authorization system, as it applies to the prescription drug program, is invalid because a pharmacist and not a physician makes the initial decision on a request for prior authorization.

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Petitioners (State of California, Department of Health Services) petitions for a writ of certiorari to review the judgment of the California District Court of Appeal for the Second District and the California Supreme Court in this case.

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OPINIONS BELOW

The opinion of the California District Court of Appeal for the Second District is reported at 163 Cal. App. 3d 18 (1984) and appears as Appendix A. The denial of a hearing on this matter by the California Supreme Court was issued on February 14, 1985.

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JURISDICTION

The judgment of the California District Court of Appeal was entered on December 21, 1984. (See Appendix A.) The California Supreme Court denied hearing on February 14, 1985. (See Appendix B.) The jurisdiction of this Court is invoked under 28 United States Code section 1257(c).

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STATUTORY PROVISIONS

The following are provisions of the Social Security Act, Title 42, which are involved herein:

42 United States Code section 1396a et seq.;

42 United States Code section 1963d(A)12, as supplemented by 42 Code of Federal Regulations sections

440.10-440.50, 440.120, 440.210, 440.220, 440.230(c) (1); and 45 Code of Federal Regulations section 249.10(a) (5) (i).

REASONS FOR GRANTING THE WRIT

I.

A. Introduction

In the trial court, respondents sought to enjoin petitioners from implementing section 53(2) of Assembly Bill No. 799 (1982) and the regulations promulgated pursuant to such authority. Assembly Bill No. 799 (Stats. 1982, ch. 328), enacted as an emergency measure on July 1, 1982, mandated certain cutbacks in the California Medicaid program known as "Medi-Cal."[1] Included in the mandated cutbacks was a reduction in the prescription drug benefits available to Medi-Cal beneficiaries. It should be noted that such pharmacy benefits are not required by federal law but are optional benefits which a state may include in its Medicaid program (42 U.S.C. § 1396d(a) (12)). Under Assembly Bill No. 799, the petitioner Department was required to eliminate drugs, medical supplies, nonprescription and prescription drugs from the Medi-Cal prescription drug formulary and to subject other items to the prior authorization process. Drugs and medical supplies which are on the Medi-Cal drug formulary can be dispensed by pharmacists without seeking the prior approval of a Medi-Cal field office consultant. The Medi-Cal drug formulary

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1. A copy of section 53(2) of Assembly Bill No. 799 (Stats.) 1982, ch. 328, § 53(2) can be found at C.T. pp. 172-173.

can be found in Title 22, California Administrative Code section 59999a-3. Other pharmacy benefits are available to Medi-Cal beneficiaries but only if the provider of services secures the prior approval of a Medi-Cal consultant.[2]

This system is known as the prior authorization system or the TAR process.[3] (See Tit. 22, Cal. Admin. Code, §§ 51003 and 51006.) Prior authorization, it should be noted, is not required where a service is rendered on an emergency basis. (Tit. 22, Cal. Admin. Code, § 51056 and *Margulis v. Myers,* 122 Cal.App.3d 335, 339, n.4 (1981).)

Pursuant to section 57 of the Assembly Bill No. 799,[4] the Director of the Department was required to adopt regulations to implement the reduction in pharmacy benefits. Under said section, specifically subdivision (e), the regulations were to be adopted as emergency regulations in accordance with Government Code section 11340 et seq., with the exception that the regulations were not to be subject to the approval and review of the Office of Administrative Law.

Pursuant to the directive of section 57 of Chapter 328, then Director Myers promulgated the required reg-

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2. The standard for approval of a request for prior authorization is set forth in Welfare and Institutions Code section 14133.3 which provides in pertinent part:

> "The director shall require fully documented medical justification from providers that the requested services are *medically necessary to protect life or prevent significant disability,* on all requests for prior authorization." (Emphasis added.)

3. TAR stands for Treatment Authorization Request.

4. A copy of Stats. 1982, ch. 328, section 57 can be found as Appendix C.

ulations and filed them with the Secretary of State effective September 1, 1982. The regulations, sections 59998 and 59999 of Title 22, California Administrative Code, were amended versions of their predecessors with the same numbers.[5] Essentially, these new regulations eliminated certain drugs and medical supplies from the Medi-Cal program and subjected some drugs, which were not previously subject, to the prior authorization procedures (TAR process).

In implementing the drug cutback, the Director of the Department was to base drug eliminations on standards of cost, critical therapeutic importance, safety, efficacy and need. Moreover, it was the stated intent of the Legislature that the Department "give priority consideration to the elimination of common medicine chest medical supply items, over the counter drug products, prescription drug products which afford minor symptomatic relief, and codeine and other narcotic analgesics." (Stats. 1982, ch. 328, § 53(2).)

Respondents urged the trial court that the Department's action in eliminating certain drugs from the program and subjecting others to the prior authorization system violated state and federal law, and that they would be irreparably harmed if a preliminary injunction was not issued pending a trial on the merits of this action. The trial court, mindful of the requirements for the issuance of an injunction pendente lite, denied respondents' request. The Court of Appeal, however, reversed the trial court and held that the trial court had abused its discretion

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5. Copies of the pre-Assembly Bill regulations and the post-Assembly No. 799 regulations can be found at C.T. pp. 175-214.

in denying respondents' request. In so doing, the Court of Appeal found that the respondent had established that "[t]heir irreparable harm outweighed any irreparable harm to the Department and the general public. . . ." (Dist. Ct. App. Opn. at p. 17.) More importantly, however, the Court of Appeal held that the trial court had abused its discretion in reaching its conclusion that respondents had not met their burden in establishing that they were likely to succeed on the merits of the action. Although the respondents advanced numerous arguments why the drug program changes were invalid, the Court of Appeal found it necessary to reach only three of these arguments. The focus of this Writ will be on these three issues, each of which was decided incorrectly.[6]

B. Statement of the Case

On August 30, 1982, respondents filed a complaint for declaratory relief and preliminary and permanent injunction. Respondents therein sought to enjoin petitioners herein from implementing any of the prescription drug program cuts mandated by Assembly Bill No. 799.

On August 31, 1982, respondents applied for and were granted an Order to Show Cause re Preliminary Injunction and Temporary Restraining Order by the Honorable Leon Thompson, Judge of the Superior Court of Los Angeles County. Said temporary restraining order, however, only granted the named individual plaintiffs relief

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6. While the petitioners do not concede that respondents met their burden of establishing that their irreparable harm outweighed the irreparable harm to the Department and the general public, this issue will not be discussed herein. If a hearing is granted in this case, petitioners will submit a supplemental brief on this issue.

and allowed the Department to implement the proposed cutbacks with respect to all persons not named parties to the action.

Thereafter, on or about September 1, 1982, respondents filed a First Amended Complaint for Declaratory Relief and Preliminary and Permanent Injunctions and Petition for Writ of Mandate.[7] On September 2, 1982, the Honorable Leon Savitch, Judge of the Superior Court, upon respondents' application issued a new Order to Show Cause re Preliminary Injunction and Temporary Restraining Order. At that time, Judge Savitch ordered that a hearing would be held on September 22, 1982 to determine whether the petitioners should be enjoined from implementing the proposed cutbacks in the Medi-Cal prescription drug program as mandated by section 53(2) of Assembly Bill No. 799. The temporary restraining order issued by Judge Savitch restrained the petitioners from implementing every aspect of those cutbacks until a hearing on the Order to Show Cause could be held.

On September 22, 1982, the hearing on the Order to Show Cause was held and Judge Savitch granted respondents a preliminary injunction which was not as broad as the temporary restraining order which was issued on September 2, 1982. More specifically the court's order prohibited the Department from implementing a portion of the proposed cutbacks. Said order granting a preliminary injunction filed and signed on October 1, 1982, states in relevant part:

> "IT IS HEREBY ORDERED that the above-named defendants shall be enjoined and restrained

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7. Respondents herein filed an Answer to said first amended complaint on October 13, 1982. (C.T. pp. 539-544.)

pending the completion of public hearings pursuant to Government Code section 11346.1(e) from removing or deleting the Medi-Cal Program drugs contained in the following classifications under the authority of Assembly Bill No. 799, section 53(2) or the regulations promulgated in connection therewith:

"1. Anticholinergic agents (parasympatholvtics), except atropine, belladonna alkaloids with phenobarbital.

"2. Antihistamines, antihistamine - containing combinations, and antipruritics.

"3. Narcotic Analgesics (other than codeine), alone or in combination, except those requiring triplicate prescriptions.

"4. Cough preparations, expectorants, and nasal decongestants, alone or in combination.

"5. Non-narcotic analgesics.

All other relief requested is denied without prejudice."

Under that order the Department could not remove certain drugs, which it intended to remove, from the Medi-Cal drug formulary. The Department was, however, free to implement that portion of the intended cutback plan which required that prior authorization be secured for certain drugs which were previously not subject to the TAR process. The most significant part of Judge Savitch's order, however, was that it was limited in time. The order by its very terms limited the duration of the injunction to the date on which the Department completed

the public hearings which were to be held regarding the cutbacks being challenged by the appellants.

The above-mentioned public hearings were held and completed on November 18 and 19, 1982. On November 16, 1982, respondents made an ex parte application to extend the effect of the preliminary injunction which Judge Savitch had issued on October 1, 1982 in accordance with his September 22, 1982 ruling. The reason for such a request was that respondents felt that the injunction should remain in effect until the Department could evaluate the public comments made at the public hearing relative to the proposed changes in the Medi-Cal prescription drug program.

The trial court agreed with respondents and on November 16, 1982, issued an Order Modifying Preliminary Injunction which extended the force and effect of its October 1, 1982 order to December 3, 1982. Faced with the impending automatic dissolution of the preliminary injunction, respondents on November 18, 1982, filed another Motion for Modification of Preliminary Injunction Order. In this motion respondents requested that the court order that the preliminary injunction issued on October 1, 1982 and modified on November 16, 1982 be extended again.

On December 3, 1982, respondents' Motion for Modification of Preliminary Injunction Order was heard by Judge Savitch. At the same time, Judge Savitch heard a Motion for Preliminary Injunction made by plaintiffs in a similar case entitled *"Rosina Fabach, etc. v. Beverlee A. Myers, et al.,"* Los Angeles Superior Court Case No. 432321.

The trial court, having considered all pleadings, respondents' moving papers and petitioners' opposition pa-

pers filed in *Fabach v. Myers,* Los Angeles Superior Court Case No. C432321, and having heard oral argument, issued an order denying respondents' Motion for Modification of Preliminary Injunction Order. In that same order, the court below acknowledged the dissolution of all previous injunctive orders. Respondents then filed an appeal from the court's order.

On March 14, 1985, upon return of the case to the trial court, the following injunctions in pertinent part were issued:

> The Court having considered the decision of the court of Appeal in *Anna Jeneski, et al. v. Beverlee A. Myers, et. al.,* 2d Civ. No. B001328, filed December 21, 1984, hearing denied, February 14, 1985, and having consulated with counsel be and hereby are, enjoined and restrained pending the determination of this action from implementing and carrying out those portions of Regulations R-44-82 and R-77-82 (codified in 22 California Administrative Code §§.59998, 59999) which (1) remove from Medi-Cal Program coverage all or some of the drugs contained in the following six therapeutic drug categories:
>
> —Antimalarials;
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> —Anticholinergics;
>
> —Antihistamines, antihistamine-containing combinations, and antipruritics;
>
> —Analgesics (narcotic and non-narcotic);

—Expectorants, cough preparations and nasal decongestants;

—Opthalmic decongestants;

and (2) transfer all or some of the drugs contained in the following three therapeutic drug catgories from Medi-Cal Formulary to prior authorization status:

—Sedative/hypnotics;

—Dermatological preparations;

—Diuretics.

Also on the same day, the court issued an injunction in the companion case of *Fabach, et al. v. Kenneth Kizer, M.D., et al.*, case number C432321.

"IT IS HEREBY ORDERED that the defendants be and hereby are, enjoined and restrained pending the determination of this action from implementing and carrying out those portions of Regulations R-44-82 and R-77-82 (codified in 22 California Administrative Code §§ 59998 and 59999) which transfer all or some of the drugs contained in the following four therapeutic drug categories from Medi-Cal Formulary to prior authorization status:

—Sedative/hypnotics;

—Dermatological preparations;

—Diuretics.

"IT IS FURTHER ORDERED that defendants may adopt emergency regulations to implement the provisions of this order, but this provision is not intended to delay the immediate effectiveness of this order."

II. The Trial Court Correctly Denied Respondents' Motion For Modification Of The Preliminary Injunction Because Respondents Did Not Establish That They Were Likely To Succeed On The Merits Of This Action.

A. The Reduction in Benefits in the Prescription Drug Program Does Not Violate the Provisions of 42 C.F.R. Section 440.230(c) (1).

Respondents argued unsuccessfully in the trial court that changes in the Medi-Cal drug program, which were mandated by Assembly Bill No. 799, violated 42 C.F.R. section 440.230(c) (1) in that the Department was denying services based upon diagnosis, type of illness or condition. Petitioners were successful in convincing the trial court that this federal regulation had no applicability to an optional service such as the prescription drug program.

The Court of Appeal, however, concluded otherwise. It concluded that 42 C.F.R. section 440.230(c) (1) applies to optional as well as required services. (See Dist. Ct. App. Opn., pp. 19-20, especially fn. 9 at p. 19, set forth in App. C.) Moreover, apparently relying on the applicability of 42 C.F.R. section 440.230(c) (1), the Court of Appeal found that the changes made in the drug program were illegal because such changes resulted in the denial of drugs to beneficiaries based upon the medical disorders from which they suffer. (See Dist. Ct. App. Opn., pp. 25-26.) The clear language of 42 C.F.R. section 440.230 (c) (1) refutes both respondents' and the Court of Appeal's construction of that section.

Title XIX of the Social Security Act, 42 U.S.C. section 1396a et seq. requires states participating in the Medi-

caid program to provide five general categories of services to qualified beneficiaries. However, even in these required services, not all medical treatments must be included. (*Beal v. Doe,* 432 U.S. 438 (1977).) States are also free to offer other services which are commonly referred to as "optional services." Prescription drugs is one of these optional benefits. (42 U.S.C. § 1396d(a) (12).)

The regulation at issue, 42 C.F.R. section 440.230(c) (1) reads as follows:

> "The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a *required service under sections 440.210 and 440.220* to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." (Emphasis added.)

The very language of the relevant federal regulation does not prohibit states from reducing the amount of an optional benefit based upon diagnosis, type of illness or condition. 42 C.F.R. section 440.230(c) (1) refers specifically to "required services" under 42 C.F.R. sections 440.210 and 440.220. Said sections do not require prescription drug services (42 C.F.R. § 440.120).[9]

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9. 42 C.F.R. section 440.210 requires that states provide the categorically needy with the services specified in 42 C.F.R. sections 440.10-440.50 and 440.70. Section 440.10 covers inpatient hospital services; section 440.20 covers outpatient hospital services and rural health clinic services; section 440.30 covers other laboratory and x-ray services; section 440.40 covers skilled nursing services (with limitations); section 440.50 covers physicians' services; and section 440.70 covers home health services. 42 C.F.R. section 440.220 (which applies to the medically needy) similarly does not include the requirement that prescription drug services (42 C.F.R. § 440.120) be provided.

The precise issue of whether 42 C.F.R. section 440.230 (c) (1) applies to optional services which are provided in Medicaid programs was decided in *Ledet v. Fischer*, 548 F.Supp. 775 (M.D. La.). Plaintiff in that case argued that eyeglasses, though an optional benefit (42 C.F.R. § 440.-120), were a required service under 42 C.F.R. section 440.230(c) (1) because it was voluntarily offered by the state.[10] Louisiana limited its eyeglass program to the provision of one pair of permanent cataract glasses following cataract surgery. In rejecting this argument the district court in *Ledet* states:

> "An otherwise 'optional' service does not become 'required' simply because it is voluntarily offered by the State. Therefore, this court concludes that plaintiff is unlikely to establish a conflict between the Louisiana eyeglass program and 42 C.F.R. section 440.230 (c) (1). The prohibition contained in Section 440.230 (c) (1) against reduction in services based on medical diagnosis has no application to the Louisiana program because it is not a 'required' program. The regulation, by its own terms, is limited to 'a service required under sections 440.210 and 440.220.' As we have seen, the Louisiana program is not 'required' by these regulations; instead, it is 'optional' under 42 C.F.R. section 440.120."

It is clear that *Ledet* is in accord with petitioners' construction of the plain meaning of 42 C.F.R. section 440.-230(c) (1). A close examination of the cases relied on by

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10. It is significant to note, as will be discussed shortly, that the court in *Ledet* was considering the same version of 42 C.F.R. section 440.230(c) (1) that is in issue herein, i.e., post 1978.

the Court of Appeal will reveal its incorrect reliance on other case law.

In reaching its conclusion that 42 C.F.R. 440.230(c)(1) applies to optional as well as required services, the Court of Appeal relied on two cases.[11] The first case is *White v. Beal*, 555 F.2d 1146, 1149 (3d Cir. 1977). At issue in *White* was the eyeglass optional benefit and whether the Commonwealth of Pennsylvania could limit that benefit to persons suffering from eye disease or pathology, thereby excluding such benefit from beneficiaries with other diagnoses. The court in *White* held that Pennsylvania could not limit the scope of this optional benefit because of the requirement set forth in 45 C.F.R. section 249.10(a)(5)(i).[12] Said section is quoted at page 1151 of the court's opinion in *White* as follows:

> "45 C.F.R. section 249.10(1)(5)(i) provides that a state plan must:
>
> > 'Specify the amount and/or duration of each item or medical and remedial care and services that will be provided to the categorically needy and to the medically needy, if the plan includes this latter group. Such items must be sufficient in amount, duration and scope to reasonably achieve

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11. See footnote 9 at page 19 of the District Court of Appeal Opinion.

12. This section is the predecessor section to 42 C.F.R. section 440.230(c)(1). 45 C.F.R. section 249.10(a)(5)(i) was enacted on May 10, 1974 (see 39 Fed. Reg. 16,971 (1974)). Said section was recodified as part of 42 C.F.R. on September 30, 1977. (See 42 Fed. Reg. 52,827 (1977).) On September 29, 1978, 42 C.F.R. section 440.230(c)(1) was enacted in its present form (see 43 Fed. Reg. 45,224 (1978)).

> their purpose. *With respect to the required services* for the categorically needy . . . and the medically needy . . . the State may not arbitrarily deny or reduce the amount, duration, or scope of, such services to an otherwise eligible individual solely because of the diagnosis, type of illness or condition. Appropriate limits may be placed on services based on such criteria as medical necessity or those contained in utilization or medical review procedures' (emphasis supplied)."

Based upon 45 C.F.R. section 249.10(1) (5) (i) the *White* court concluded that Pennsylvania's limitation on the eyeglass program was unlawfully denying benefits based upon diagnosis. The hold in *White*, however, has no applicability to the case herein. *White* was decided in May of 1977 prior to the enactment of 42 C.F.R. section 440.230(c) (1) in 1978). While 45 C.F.R. section 249.10(a) (5) (i) did not define "required services" in its text, 42 C.F.R. section 440.230(c) resolved this problem and limited its applicability to required services by its very terms defining required services as those set forth under 42 C.F.R. sections 440.210 and 440.220. Accordingly, it is submitted that *White v. Beal* provides no authority whatsoever for the Court of Appeal's conclusion that 42 C.F.R. section 440.230(c) (1) can be applied in reviewing petitioners' implementation of the changes in the prescription drug program which were mandated by the Legislature.

Likewise, the Court of Appeal's reliance on *Simpson v. Wilson*, 480 F.Supp. 97 (D.Vt. 1979) is misplaced. In *Simpson*, plaintiffs challenged the State of Vermont's practice of excluding eyeglasses to correct visual refractive errors from coverage in the optional eyeglass bene-

fit of its Medicaid program. One of the plaintiffs' arguments was that in so doing, Vermont was denying a benefit based upon diagnosis, type of illness or condition in violation of 42 C.F.R. section 440.230(c) (1). The court agreed and concluded that 42 C.F.R. section 440.230(c) (1) was applicable to optional services. The only authority the *Simpson* court cited for reaching this conclusion, however, was *White v. Beal.* Moreover, the court in *Simpson*, for some unknown reason in quoting 42 C.F.R. section 440.230 (c) (1) conveniently deleted the qualifying language which defines "required services".[13] Suffice it to say that *Simpson* also does not provide any sound precedent for the proposition that 42 C.F.R. section 440.230(c) (1) applies to optional benefits in the Medicaid program.

In summary, the California District Court of Appeal was wrong in its determination that the trial court abused its discretion by finding respondents were likely to succeed on the merits of their argument that the subject prescription drug cutback violated the provisions of 42 C.F.R. section 440.320(c) (1). This Court must grant a hearing in this matter to rectify this error which, if left to stand, will discourage the legislatures throughout the nation from maintaining optional benefits.

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13. The court quotes 42 C.F.R. section 440.230(c) (1) as follows:

> "The prohibition against denying or reducing 'the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition,' id. sec. 440.230(c) (1), also applies to optional services. White, 555 F.2d at 1151-52." (*Simpson, supra*, at p. 102.)

B. The Prior Authorization System Does Provide for Appeal Hearings for Beneficiaries and Providers Whose TARs for Prescription Drugs Are Initially Denied and, Therefore, the Prior Authorization System Is Not Invalid.

The Court of Appeal also ruled that this state's prescription drug program was not in accord with federal law because beneficiaries were not granted *pre-denial* hearings when their requests for prior authorization for certain drugs were initially denied. This issue was not raised by respondents at the trial court or before the Court of Appeal, was not briefed by any party at any stage of this litigation, and was not raised by the Court of Appeal at oral argument. It was not until the parties received the decision of the Court of Appeal that they received notice that this issue was germane to this case.

The Court of Appeal's ruling fails to acknowledge that California's Medi-Cal system does provide for appeal rights for both the beneficiary and the provider of services if a request for prior authorization is denied. These appeal rights are not discussed in the Court of Appeal's opinion and, therefore, their sufficiency is likewise not analyzed.

If a request for prior authorization is denied, the provider of services can appeal the decision of the Medi-Cal consultant. (Tit. 22, Cal. Admin. Code § 51003(g).) Such an appeal must be filed in writing and submitted to the administrator of the local Medi-Cal field office within

60 days from the date the provider is notified[14] of the Medi-Cal consultant's adverse decision. (Tit. 22, Cal. Admin. Code § 51003(g).) If the appeal is denied at the local administrator level, the provider can then appeal to the Field Services Headquarters. (Tit. 22, Cal. Admin. Code § 51003(g) (2) and (3).) Accordingly, the provider of service, in this case the pharmacist and/or prescribing physician, has two levels of appeal available to him/her if a prescription drug TAR is denied. It is significant that the provider of services is given an appeal right because it is the provider and not the beneficiary who is more likely to have the necessary medical information which would provide the basis for a successful appeal.

The Department has also provided the beneficiary, whose TAR has been denied, with an appeal procedure. A Medi-Cal beneficiary has a right to a fair hearing if he/she is dissatisfied with any action taken by the Department relating to any Medi-Cal benefit or eligibility question. (Tit. 22, Cal. Admin. Code § 50951(a).) This, of course, would include the denial of a TAR for prescription drugs. The right to such a hearing is governed by the provisions of Welfare and Institutions Code sections 10950-10965. (Tit. 22, Cal. Admin. Code § 50951(b).)[15]

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14. Notice is given to the provider of services as provided for in Title 22, California Administrative Code section 51014.1(e).

15. Beneficiaries are notified of their right to appeal and fair hearing on any action, other than approval, taken by the Department on a request on any medical service, at the time of application to the Medi-Cal program and on a quarterly basis thereafter. (Tit. 22, Cal. Admin. Code § 51014(a) (1).) Additionally, if a drug TAR is denied, the beneficiary, as well

(Continued on next page)

California Welfare and Institutions Code sections 10950-10965 set forth the evidentiary hearing procedures which are followed in welfare benefit appeals. Such hearings are conducted by impartial referees (Welf. & Inst. Code, § 10953), in an impartial and informal manner, with the opportunity to the applicant or recipient to be represented by counsel. (Welf. & Inst. Code, § 10958.) Moreover, the Department's final decision is renewable under Code of Civil Procedure section 1094.5 (Welf. & Inst. Code, § 10962). Accordingly, despite the Court of Appeal's failure to acknowledge their existence, appeals procedures for both the beneficiary and the provider do exist within the prior authorization system. These procedures provide beneficiaries and their providers with notice and an opportunity to be heard. (*Goldberg v. Kelly*, 397 U.S. 254 (1970).)

While the Court of Appeal's opinion does not thoroughly discuss the reasons why a *pre-denial hearing* is required when a TAR is initially denied, from its citation to *American Federation of Labor v. Employment Dev. Dept.*, 88 Cal.App.3d 811 (1979), it is apparent that the

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as the provider, receives notice of the initial decision of the Medi-Cal consultant. Notice is given to the beneficiary pursuant to the provisions of a preliminary injunction issued on May 2, 1984 in the matter entitled *Jackson, et al. v. Rank*, Civil Action No. CV83-1451-LKK, which is currently pending before the United States District Court, Eastern District of California. A certified copy of the aforesaid preliminary injunction is attached to the request for judicial notice which is filed concurrently herewith.

court was basing its decision on due process principles.[16] Since the Court of Appeal failed to acknowledge the existence of the appeal procedures which are discussed above, it of course did not discuss why these appeal procedures do not comport with due process principles. In any event, petitioners submit that these procedures do satisfy the dictates of due process and are not constitutionally firm.

In deciding what hearing procedures are required by due process, the court must weigh the competing interests of the individual and the government in light of the particular facts of the case. (*Arnett v. Kennedy,* 416 U.S. 134, 168 (1979).) Moreover, in determining whether a course of governmental conduct deprives a person of due process of law, it must be kept in mind that the requirements of due process are not technical nor is any particular form of procedure necessary. (*Kremer v. Chemical Construction Corp.,* 456 U.S. 461, 483 (1982).) Additionally, the function of legal due process is to minimize the risk of erroneous decisions. (*Addington v. Texas,* 441 U.S. 419, 423 (1979).) However, the due process clause does not mandate that all governmental decision making comply with standards that assure perfect error-free determinations. (*Mackey v. Montrym,* 443 U.S. 1, 13 (1979).) Ordinarily, something *less* than an evidentiary hearing is sufficient prior to adverse administrative action. (*Dixon v. Love,* 431 U.S. 105, 113 (1977) and *Mathews v. Eldridge,* 424 U.S. 319, 343 (1976).) These elementary principles should be kept in mind in determining whether the hearing

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16. See District Court of Appeal opinion at pages 23-25. *American Federation of Labor* addressed the issue of whether unemployment insurance benefits could, without violating the due process clause, be terminated without a prior hearing.

procedures discussed above comply with the requirements of due process. The United States Supreme Court in *Mathews v. Eldridge, supra,* 424 U.S. 319, 345, established the factors to be considered in determining what procedures due process will require in a given situation. These factors are:

1. The private interest that will be affected by the official action;

2. The risk of an erroneous deprivation of such interest through the procedures used and probable value, if any, of additional procedural safeguards; and

3. The government's interest, including fiscal and administrative burdens that the additional or substitute procedures would entail. (See *Matthews v. Eldridge, supra,* at pp. 343-345.)

The hearing procedures offered by the Department in this case satisfy any due process concerns.

The private interest in this case is concededly important. Petitioners do no deny that beneficiaries have a significant interest in obtaining prescription drugs to treat their illnesses and certainly governmental action in denying authorization to fill those prescriptions affects that interest. However, in analyzing the magnitude of this private interest other factors must be considered. For example, if there is an emergent need for a drug, the prior authorization need not be secured. (Tit. 22, Cal. Admin. Code § 51056.) In other words, where a beneficiary's condition rises to the level of an emergency, a drug which is normally subject to the TAR process can be dispensed without delay. Secondly, most of the drugs subjected to the prior authorization process have counter-

parts which are still available on the drug formulary without prior authorization or are available over the counter at a small cost. Accordingly, in most instances if a TAR request is denied, the prescribing physician can look to the formulary for a comparable drug or the beneficiary can purchase an over the counter item pending a hearing on the TAR denial. It is submitted, therefore, that because the TAR process is not applicable where a true emergency exists, and because comparable drugs are available in the drug formulary or over the counter at a small cost, the private interest at stake in this due process analysis is not as great as it might seem when superficially examined.

We next turn to the second factor to be considered which is the risk of erroneous deprivation which might occur through the procedures used and the probable value, if any, of additional procedural safeguards. The review process to which a TAR is subjected should leave little doubt that there is little or no risk of the erroneous denial of a request for any particular drug. First of all, only licensed pharmacists are authorized to approve or deny TARs which are received by phone or in writing. These pharmacists can and do consult with a broad based assemblage of medical consultants having a wide variety of specialties and vast accumulated practical experience. The pharmacy consultant in making his/her decision to grant or deny a TAR is not vested with unbridled discretion. He or she is guided by the statutorily defined criteria which must be met in order for a prior authorization request to be granted. (Welf. & Inst. Code, § 14133.3(a).) Additionally, Medi-Cal pharmacy consultants are required, pursuant to Title 22, California Administrative Code sec-

tion 51003(3)[17] to follow the "Manual of Criteria for Medi-Cal Authorization" which sets forth the standards to be used in evaluating TARs. This Manual of Criteria sets forth details which assist the pharmacist in determining whether a TAR should be denied or granted. Given the careful review process as outlined above, it is submitted that the risk of administrative error in reviewing drug TARs is very slight.

Given this slight chance of erroneous deprivation, we turn to the probable value of additional safeguards. Little if any value can be seen in adding yet another administrative burden to the implementation of the TAR process. The careful approval process as described above, coupled with the appeal procedures which are available to both the provider and the beneficiary provide beneficiaries with more than adequate protection against erroneous governmental action. The TAR process exempts emergency situations from its requirements, provides a system which is run by professionals who are guided by statutory and regulatory guidelines, and provides for constitutionally adequate appeal rights. Such a system does not require the use of additional procedural safeguards.

The final factor to be considered in the *Mathews* triparte test is the governmental interest, including fiscal and administrative burdens that additional or substitute procedures would entail. Clearly, the requirement that each beneficiary be given a hearing before each TAR is denied would require both substantial cost and administrative burden. Because this due process and pre-denial

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17. See also Welfare and Institutions Code Section 14133.9.

hearing issue was not an issue before the trial court, the record does not contain any evidence on the exact cost of providing pre-denial hearings and the administrative burden which would result therefrom. The record does reflect, however, the number of TARS submitted and the actions taken on these TARs in the month of October 1982. In October of 1982, the Los Angeles Medi-Cal field office processed 3,852 written and verbal (telephone) TARs. Of these 3,582, 484 were denied and another 138 were returned. Accordingly, in Los Angeles, for the month of October 1982, there were at least 622 appeals possible. Additionally, for the first ten days of November 1982, there were 1,152 TARs processed and of those 310 were denied and 133 were returned. For the first ten days of November 1982, there were, therefore, at least 433 possible appeals.[18] These numbers are not insubstantial and at least provide this Court with some idea of the magnitude of a pre-denial hearing process which would have to be implemented in order to meet the requests for such hearings. It is obvious that the cost of providing such hearings would be substantial. Also to be included in the administrative burden which would result from pre-denial hearings is the disruption of the ongoing approval process. A consultant who denied the initial TAR request would most likely become involved in this pre-denial hearing which would take him or her away from his or her regular duties. Suffice it to say that the sheer number of potential appeals would result in substantial administrative burdens.

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18. Similar statistics for the San Francisco field office can be found in the record below.

In conclusion, given the nature of the right at stake, the availability of post-denial remedies and the administrative burden that pre-denial hearings would cause, the appeals process available to unsuccessful TAR applicants satisfies the requirements of due process as outlined in *Mathews v. Eldridge.*

C. The Prior Authorization System Is Not Invalid Because a Pharmacist and Not a Physician In The First Instance Rules On a TAR.

The Court of Appeal also ruled that California's prior authorization system was invalid, with respect to prescription drugs, because a pharmacist and not a physician makes the initial decision on a TAR. (See Dist. Ct. App. Opn. at pp. 22-23.) The court in reaching this conclusion relied wholly on *Dodson v. Parham,* 427 F.Supp. 97 (N.D. Ga.) and the reasoning that it is "unrealistic for defendants to presume that a doctor of pharmacy is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval of a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom he is intimately familiar." The Court of Appeal pointed to no evidence in the record herein which supports this "logic."

The Court of Appeal's reliance on *Dodson* is misplaced because it ignores the factual differences between Georgia's prior approval system and California's prior approval system as it is applied to the prescription drug program. In California, although the licensed doctor of pharmacy makes the initial decision on a drug TAR, he or she does not make a decision in a vacuum. The pharmacy

consultant has a broad range of medical consultants who are available to him or her for consultation on whether a TAR should be granted or denied. Nowhere in the *Dodson v. Parham* case does the court indicate that similar medical consultation is available in the Georgia prior authorization system. Moreover, California pharmacist-consultants must follow a detailed Manual of Criteria for Medi-Cal Authorization which sets forth in a detailed manner the criteria which are to be followed in ruling on a TAR. There is nothing in the *Dodson* case which indicates that Georgia's pharmacists are similarly restrained. It is clear, therefore, tha Georgia's and California's use of pharmacists in the prior approval process are dissimilar and that *Dodson v. Parham* is not persuasive.

The bottom line to the pharmacist versus physician argument is that respondents feel that physicians' discretion is being intefered with when the pharmacist makes a ruling on a TAR. While it is true that the Congress has put some emphasis on physician discretion, it is not logical to conclude that Congress intended that every physician be allowed to prescribe every drug on the market to a Medi-Cal patient at the State's expense. Federal Medicaid law does not require that physicians be given total uncontrolled discretion in treating their patients. Reasonable limitations on the treating physician's judgment are unavoidable and justified. (*Rush v. Parham,* 625 F.2d 1150 (5th Cir. 1980); *Doe v. Beal,* 523 F.2d 611, 621 (3d Cir. 1975); *Coe v. Hooker,* 406 F.Supp. 1072, 1082 (D.N.H. 1976).) Department pharmacists, in ruling on TARs, are not second guessing the treating physician but are merely ensuring that the prescribed drug is reimbursable under the statutory and regulatory limitations which the Legis-

lature and the Department have enacted and promulgated. Accordingly, it is submitted that the use of a pharmacist in the TAR process does not under the facts of this case invalidate the prior authorization system.

CONCLUSION

For the reasons stated, the Writ of Certiorari should be issued.

Respectfully submitted,

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APPENDIX A

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE
STATE OF CALIFORNIA
SECOND APPELLATE DISTRICT
DISTRICT THREE

2D CIV. NO. B001328

(Super.Ct.No. C 423494)

ANNA JANESKI, WILLIAM SWAIN,
EDITH PANTILLA, and ARTHUR COLVIN,

Plaintiffs and Appellants,

vs.

BEVERLEE A. MYERS, Director of the Department of Health Services; EDMUND G. BROWN, JR., Governor of the State of California; STATE OF CALIFORNIA, a political entity,

Defendants and Respondents.

(Filed Dec. 21, 1984)

APPEAL from the orders of the Superior Court, Los Angeles County. Leon Savitch, Judge. Reversed.

Marks and Stevenson and Ronald S. Marks, for Plaintiffs and Appellants.

John K. Van de Kamp, Attorney General, Thomas E. Warriner, Assistant Attorney General, Anne S. Pressman and Louis Verdugo, Jr., Deputy Attorneys General, for Defendants and Respondents.

National Health Law Program, Inc., Michael C. Parks and Michael A. Dowell, and Legal Aid Foundation of Los Angeles and Bruce Iwasaki for Amicus Curiae.

Plaintiffs and appellants are Medi-Cal recipients who sought to have the trial court enjoin respondent Department of Health Services (Department), its director, and the Governor from implementing a statute and regulations that deleted certain drugs from a list of those for which Medi-Cal would reimburse and put other drugs on a list for which prior authorization was required.[1] The trial court initially granted an order to show cause re preliminary injunction and a temporary restraining order,

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[1] The statute, originally designated California Assembly Bill No. 799 (AB 799), was enacted as emergency legislation. Section 53(2) of the bill was intended to delete $20,000,000 and then $16,000,000, in an amended version, from the general fund. Statutes 1982, Chapter 328, section 53(2), page 1606 provides: "It is the intent of the Legislature to reduce pharmacy program expenditures . . . by 20 million dollars ($20,000,000) General Fund money. To achieve this savings goal, the department shall eliminate drugs, medical supplies, nonprescription and prescription drugs from the Medi-Cal Drug Formulary, or from the Medi-Cal program, and implement other utilization controls for retained items. In implementing this provision, the director shall determine which drugs shall be eliminated based on standards of cost, critical therapeutic importance, safety, efficacy and need. It is the intent of the Legislature that, in making these reductions, the department shall give priority consideration to the elimination of common medicine chest medical supply items, over-the-counter drug products, prescription drug products which afford minor symptomatic relief, and codeine and other narcotic analgesics. In implementing this provision, the director of health services shall not be required to comply with the provisions of sections 14053.5 and 14184 of the Welfare and Institutions Code, insofar as the latter section requires the director to receive a report from the Medical Therapeutic Drugs and Advisory Committee prior to making determinations as to the additions and deletions from the formulary."

R-44-82 (Tit. 22, Cal. Admin. Code, §§ 59998-59999), the regulation implementing AB 799 deleted some drugs from the Formulary and required prior authorization for others. Some medications with codeine, at first deleted, were later reinserted.

limited to the named Medi-Cal recipients.[2] The hearing on the order to show cause was set for September 22, 1982. After the first amended complaint was filed, a second judge issued a new order to show cause regarding the preliminary injunction. The temporary restraining order, dated September 2, 1982, restrained respondents from "[i]mplementation of Section 53(2) of AB799 and implementation of Title 22, California Administrative Code sections 59999 a-e (Drug Formulary Section) and Title 22, California Administrative Code sections 51003 and 51056 (TAR and Emergency Sections) as they apply to Section 59999 a-e."[3]

On September 22, 1982, a hearing was held purrsuant to the order to show cause. In an order dated October 1, 1982, Judge Leon Savitch ordered that respondents are "hereby enjoined and restrained *pending the completion of public hearings* pursuant to Government Code section 11346.1(e) from removing or deleting from the Medi-Cal Program drugs contained in the following classifications under the authority of Assembly Bill No. 799, section 53(2) or the regulations promulgated in connection therewith: [¶] 1. Anticholinergic agents (parasympatholytics), except atropine, belladonna alkaloids with phenobarbital. [¶] 2. Antihistamines, antihistamine-containing combinations, and antipruritics. [¶] 3. Narcotic anal-

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[2] The original complaint named other plaintiffs as well; a first amended complaint dropped the plaintiffs who were not individual Medi-Cal recipients.

[3] "TAR" stands for treatment authorization request and involves the procedures for prior authorization of drugs requested by Medi-Cal recipients, their pharmacists, and doctors. The prior authorization is sought on a patient-by-patient basis and is requested by the Medi-Cal providers.

gesics (other than codeine), alone or in combination, except those requiring triplicate prescriptions. [¶] 4. Cough preparations, expectorants, and nasal decongestants, alone or in combinations. [¶] 5. Non-narcotic analgesics." (Emphasis added.) All other relief was denied without prejudice.

Responding to appellants' request to extend the injunction so that the Department could evaluate the comments made at public hearings on November 18 and 19, 1982, the court issued an order modifying the preliminary injunction and extended the force and effect of its October 1 order to December 3, 1982. However, a further request by appellants to modify the injunction (1) to extend its effect until the regulations were adopted and (2) to enjoin deletion of dermatological anti-inflammatory and hypnotic/sedative classifications, currently subject to the prior approval process, as well as anti-arthritic drugs, was denied in an order filed December 9, 1982. In addition, the court also ordered that the preliminary injunction issued October 1, as modified on November 16, "is hereby dissolved."

Appellants' notice of appeal states that the appeal is from "the judgment of the above-entitled Court . . . entered December 3, 1982 [sic], dissolving the Preliminary Injunction issued on September 22, 1982, and denying Plaintiffs' request to modify said Preliminary Injunction as prayed for in Plaintiffs moving papers."

GENERAL BACKGROUND

Title XIX of the Social Security Act, 42 U.S.C. section 1396, et seq., "establishes the Medicaid program under which participating States may provide federally

funded medical assistance to needy persons. The statute requires participating States to provide qualified individuals with financial assistance in five general categories of medical treatment." (Fns. omitted; *Beal v. Doe* (1977), 432 U.S. 438, 440.) "If the state wishes to maintain a more comprehensive program, it may provide seven of sixteen listed benefits [including prescription drugs][4] to the less poor, characterized as the 'medically needy.' 42 U.S.C. § 1396a(a)(13)(C). A state providing specific services for the 'medically needy' must also provide them for the 'categorically needy.' [Citations.] Moreover, all persons within a given category must be treated equally." (*White v. Beal* (3d Cir. 1977), 555 F.2d 1146, 1149.)

"A state may pay 'part or all of the cost . . . of care and services,' 42 U.S.C. § 1396d(a), but it 'may not deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.' 42 C.F.R. § 440.230(c)(1) (1978). Although a state 'may place appropriate limits on a service based on medical necessity or on utilization control procedures,' *id.* § 440.230 (c)(2), '[e]ach service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.' *Id.* § 440.230(a)." (*Simpson v. Wilson* (D.Vt. 1979) 480 F.Supp. 97, 100.)

Courts have noted "[t]he significance of Medicaid, and the individual and collective human suffering which it ameliorates, rehabilitates, and forestalls. . . ." (*Bass*

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[4] California has chosen to cover the "[p]urchase of prescribed drugs . . . subject to the Medi-Cal Drug Formulary and utilization controls." (Welf. & Inst. Code, § 14132, subd. (d).)

v. Richardson (S.D.N.Y. 1971) 338 F.Supp. 478, 483.) And, while courts are cognizant of the need for fiscal economy, "budgetary constraints cannot excuse a failure to comply with federal standards." *(California Ass'n of Bioanalysts v. Rank* (C.D.Cal. 1983), 577 F.Supp. 1342, 1353, fn. 14.)

FACTS[5]

Appellants filed numerous declarations in support of their requests for injunctive relief and modification. Medi-Cal recipients, doctors, and pharmacists declared the hazards of removing antihistamines, topical dermatological preparations, cough and cold preparations, and other prescription drugs from the Medi-Cal formulary. One dermatologist declared the system a "mockery of any attempt to impart any rational health care to the needy." Another physician stated that the new system constituted a "clear class system of medical treatment" and a "double standard of health care." Another doctor stated that the new system would "severely restrict my ability to effectively treat my patients, and is a rather insensitive and callous act on the part of the Legislature." Another dermatologist deemed it "pure idiocy."

They detailed the hazards to patients, including "dire life-threatening effects."[6] In addition, they asserted that

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[5] The record on appeal consists of a two-volume clerk's transcript and two additional volumes of exhibits pursuant to stipulation to augment the record.

[6] Section 38 of AB 799 added section 14133.3 to the Welfare and Institutions Code, which provides in pertinent part:

(Continued on next page)

the new plan would be more costly in that minor problems would not be handled and thus would escalate into more serious medical problems that would require hospitalization and more expense for the state. The dangers of the alternative drugs were also outlined.

Declarations filed by appellants and in the companion case of *Fabach v. Myers* (No. C 432321), attempt to demonstrate that prior authorization approvals are "essentially unavailable." The added documentation for physicians and pharmacists is seen as unduly time consuming. As one dermatologist declared, it "makes it totally impractical for me to continue even attempting to treat these patients." Others declared that an overwhelming percentage of TAR requests were rejected on the basis that the patient's ailment was not "life threatening" and some believed that the TAR offices were utilizing delaying tactics in order to discourage applications for TARs. Some believed that it would be virtually impossible for the TAR offices to process the requests in a timely manner and that for all intents and purposes TARS will be unavailable to the Medi-Cal recipient.

As stated in the memorandum of points and authorities in opposition to the OSC re preliminary injunction in the *Fabach* case respondents conceded that there is no "joy in implementing the required cutbacks." Neverthe-

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"The director shall require fully documented medical justification from providers that the requested services are *medically necessary to protect life or present significant disability,* on all requests for prior authorization." (Emphasis added.) Before the enactment of AB 799, one had to demonstrate only that the treatment was "medically necessary."

less, declarations in support of respondents' position stated that the basis for the reduction was the legislative standard of "cost, critical therapeutic importance in relation to the universe of available pharmaceuticals, safety, efficacy, and need." The purpose, which respondents believe they achieved, was to effect the required savings with the least possible adverse impact upon the beneficiary community. A declaration of respondent Myers states that the Department sought to promulgate a plan "least harmful of all possible alternatives to the health, safety and wellbeing of the beneficiary community."

Dr. Toshiko Iwata, a physician and pharmacist employed as a senior medical consultant in the Medical Policy and Standards Section of the Benefits Branch in the Department of Health Services, stated that the elimination of various categories of drugs "will not have dire life-threatening effects upon the Medi-Cal population. . . ." Rather, he believes that " 'the injudicious use of medication should be discouraged . . .' " and that, in any event, many of the drugs are over-the-counter drugs that historically have not been reimbursed by the program and that other drugs that have remained within the formulary can substitute for those that have been eliminated. William A. White, who directs the development of policies regarding drugs and medical supplies for the Department of Health Services, after explaining the process of decision on which drugs would be restricted or eliminated, concluded: "I believe that the carefully considered reductions in drug coverage proposed by the Department can be effected with no significant impact on the health of Medi-Cal beneficiaries." Admitting that "the choices were very difficult," Allen Fung, a pharmacist who is senior

consulting pharmacist for the Medi-Cal Benefits branch of the California Department of Health Services in Sacramento, described the process of carrying out the legislative mandate to cut back on Medi-Cal drug provisions. His declaration explains the reasons for eliminating various categories of drugs and for putting others in the category requiring prior authorization. He concluded that the "cutbacks as described are, in my opinion, the least detrimental to both groups [Medi-Cal beneficiaries, and pharmacists and doctors] that could be devised, consistent with the cost savings mandated by the Legislature."

Other declarations provided by respondents corroborate the careful planning by the Department of Health in making the necessary decisions and in refuting appellants' position that the TARs would be virtually unobtainable.

CONTENTIONS ON APPEAL

Appellants make the following contentions challenging the validity of the Medi-Cal cutbacks:

1. The court erred in dissolving the preliminary injunction since no new facts or law were presented that refuted the court's original findings.

2. The trial court erred in failing to maintain a preliminary injunction in effect since the subject regulation violates the "sufficiency" requirement of 42 C.F.R. section 440.230(b).

3. The subject regulation violates the "simplicity of administration" and "best interest of the patient" requirements of 42 U.S.C. section 1396(a)(19).

4. The subject regulation limits a physician in the exercise of medical judgment, which is inconsistent with the intent of the federal law.

5. The regulation implementing the new drug formulary violates Title XIX of the Social Security Act's mandate of equality and therefore is invalid.

6. The subject regulation arbitrarily denies the amount, duration, or scope of medical services to Medi-Cal recipients because of diagnosis, type of illness, or condition, in violation of federal law.

7. The subject regulation reprives MediCal patients of the rights secured to them by 42 U.S.C. section 1396(a)(19), in violation of the equal protection clause of the Fourteenth Amendment.

8. The subject regulation denies Medi-Cal patients their constitutional right to an evidentiary hearing prior to termination of their medical benefits in violation of the Fifth and Fourteenth Amendment to the federal Constitution.

9. The subject regulation is void and contrary to the law in that it discriminates against eligible Medi-Cal recipients based purely on their economic disability.

10. Section 53(2) of AB 799 conferred upon the director of Health Services an unconstitutional delegation of power.

11. The subject regulation is an unconstitutional restraint on those Medi-Cal patients exercising their fundamental rights guaranteed by the California Constitution.

A brief filed as amicus curiae[7] in support of appellants contends that the trial court abused its discretion in denying appellants' motion to modify the preliminary injunction. Amicus argues that appellants were likely to prevail on the merits in that (1) failure to consult the State Medical Advisory Committee as required by federal law requires invalidation of the drug formulary changes; (2) federal law prohibits drug formulary reductions based on types of illness, as opposed to medical necessity; and (3) the prior approval system for certain pharmacy categories lacks the standards required by federal law.

Respondents contend that the appropriate test is whether the trial court abused its discretion in denying appellants' motion for modification of the preliminary injunction. They contend that the trial court did not abuse its discretion in denying the motion, since appellants did not show below that they were likely to prevail on the merits of this action at trial, nor did they establish that any irreparable harm that they might suffer outweighed the irreparable harm that the department and the general public might suffer if its motion to modify the preliminary injunction were to be granted. Respondents refute each of the contentions made by appellants challenging the constitutional and statutory validity of the Medi-Cal cutbacks.

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[7] The court is grateful for the work done by the National Health Law Program, Inc., and the Legal Aid Foundation of Los Angeles in preparing the brief as amicus curiae at the request of this Division.

DISCUSSION

Scope of Review

As our Supreme Court stated in *Continental Baking Co. v. Katz* (1968), 68 Cal.2d 512, 528: "'the granting or denial of a preliminary injunction does not amount to an adjudication of the ultimate rights in controversy. It merely determines that the court, balancing the respective equities of the parties, concludes that, pending a trial on the merits, the defendant should or that he should not be restrained from exercising the right claimed by him.' [Citations.] The general purpose of such an injunction is the preservation of the status quo until a final determination of the merits of the action. [Citations.] Thus, the court examines all of the material before it in order to consider 'whether a greater injury will result to the defendant from granting the injunction than to the plaintiff from refusing it; . . .' [Citations.] In making that determination the court will consider the probability of the plaintiff's ultimately prevailing in the case and, it has been said, will deny a preliminary injunction unless there is a reasonable probability that plaintiff will be successful in the assertion of his rights. [Citations.] As was said in *Family Record Plan, Inc. v. Mitchell* (1959), 172 Cal. App.2d 235, 242 [342 P.2d 10], 'In the last analysis the trial court must determine which party is the more likely to be injured by the exercise of its discretion [citation] and it must then be exercised in favor of that party [citation].'"

"'The authorities are numerous and uniform to the effect that the granting or denial of a preliminary in-

junction on a verified complaint, together with oral testimony or affidavits, even though the evidence with respect to the absolute right therefor may be conflicting, rests in the sound discretion of the trial court, and that the order may not be interfered with on appeal, except for an abuse of discretion.' [Citation.]" (*Id.*, at p. 527.) (See also *Weingand v. Atlantic Sav. & Loan Assn.* (1970) 1 Cal.3d 806, 820.)

1. *The Preliminary Injunction Dissolved By Its Own Terms; Appellants did not Demonstrate a Change in the Controlling Facts*

Appellants contend that the trial court erred in dissolving the preliminary injunction since no new facts or law were presented that refuted the court's original findings. It is true that "when it is shown that '"there has been a change in the controlling facts upon which the injunction rested, or *the law has been changed, modified or extended,* or where . . . the ends of justice would be served by modification,"' the trial court has the inherent power to modify or vacate the injunction [citations]." (Emphasis in original.) (*M Restaurants, Inc. v. San Francisco Local Joint Exec. Bd. Culinary etc. Union* (1981), 124 Cal. App.3d 666, 674.)

Respondents did not ask for the injunction to be dissolved. Rather, the injunction itself ordered that respondents be restrained "pending the completion of public hearings . . . ." The court permitted a further extension past the public hearings held on November 18 and 19, so that the department could evaluate the comments made at the public hearings. It is appellants and not respondents who had the burden to show a further change in circumstances

in order to justify modification of the terms of the preliminary injunction. We have reviewed appellants' memorandum of points and authorities in support of the modification of preliminary injunction; appellants did not meet their burden of demonstrating a change of circumstances.

2. *The Trial Court Abused Its Discretion In Denying Appellants' Motion for Modification of the Preliminary Injunction*

Respondents contend that appellants showed neither that they were likely to prevail on the merits of the action at trial nor that any irreparable harm they might suffer outweighed the irreparable harm that the Department and the general public might suffer if appellants' motion to modify the preliminary injunction were to be granted. We find the second point to be without merit. Assuming *arguendo* that appellant Medi-Cal recipients were illegally denied drugs that were medically necessary, we believe appellants did establish that their irreparable harm outweighed any irreparable harm to the Department and the general public in denying the motion to modify and extend the effect of the preliminary injunction. Therefore, we need only discuss whether appellants demonstrated they were likely to prevail on the merits at trial.[8]

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[8] As the court noted in *Bass v. Richardson, supra,* 338 F. Supp. at p. 489, "[t]he State cannot prevail on the balance of incredible human suffering which the amendments to this program would create. The injury to those whose health is maintained on the slenderest chemical balance provided through medication is not merely irreparable; it is ultimate."

Respondents have informed us that Medi-Cal recipients have already prevailed after trial in *Cowan v. Meyers,* now on appeal in the Third Appellate District (3d Civ. 22987). That case involves, *inter alia,* an attack on the prior authorization scheme.

3. *Appellants demonstrated that they are Likely to Prevail on the Merits at Trial*

We are assuming for the purpose of this discussion that the trial court believed the declarations presented by respondents. Although a trial with testimony by live witnesses might well present a different result, as it did in *Cowan v. Meyers* (see footnote 8), we will accept on this appeal that substantial evidence supports findings that respondents diligently attempted to reduce coverage in areas of least detriment to Medi-Cal recipients; that the TAR process is not unduly time-consuming, producing intentional delays that inhibit requests; and that prior authorizations have not been made essentially unavailable because of the way the TAR program is administered.

Our inquiry does not end with those findings. The program must still comply with the statutes and constitutional law that govern Medicaid and administrative procedures. In our view, as discussed below, the prior approval system and the general cutback do not comply with the relevant guidelines. Therefore, appellants are "likely to prevail" at trial; and the preliminary injunction should have been expanded in scope and entended in time.

Several of appellants' contentions on appeal are based in the federal statutes and regulations that govern Medicaid programs.

42 C.F.R. section 440.230(b) requires that medical services provided under the Medi-Cal program be "sufficient in amount, duration and scope to reasonably achieve

its purpose."[9] Subsection (c) of 440.230 provides in part that the Medicaid agency may not "arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." 42 U.S.C. section 1396(a)(19) requires state Medicaid plans to "provide such safequards as may be necessary to assure that eligibility for care and services under the plan will be determined and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients; . . ." 42 U.S.C. section 1396(a)(10)(B)(i) provides the medical assistance made available to any individual described in clause (a)(i) shall "not be less in amount, duration, or scope than the medical assistance made available to any other such individual, . . ." Finally, appellants rely on case law stating the purpose of the federal law is, in part, to allow a physician to decide upon medically necessary treatment, including drugs. (*Rush v. Parham* (N.D.Ga. 1977), 440 F.Supp. 383, 389).

In establishing the program in California, the Legislature in section 14000 of the Welfare and Institutions Code provided that its intent was "to provide, to the ex-

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[9] There is divergence in the cases as to whether the provisions of 42 C.F.R. section 440.230 apply to optional as well as mandatory medical services. (See *Ledet v. Fischer* (M.D. La. 1982) 548 F.Supp. 775, 786, which states it does not apply to optional services; and compare *White v. Beal, supra,* 555 F.2d 1146 and *Simpson v. Wilson, supra,* 480 F.Supp. 97.) We accept the view that once a state decides to provide an optional service, the provisions of 42 C.F.R. § 440.230 apply. The chief beneficiary of the system is the patient (*Margulis v. Myers* (1981) 122 Cal.App.3d 335, 343), and the patient's interest should be protected.

tent practicable . . . for health care for those aged and other persons, including family members who lack sufficient annual income to meet the cost of health care, and whose other assets are so limited that their application toward the costs of such care would jeopardize the person or family's future minimum self-maintenance and security." The Legislature added that "[i]t is intended that whenever possible and feasible: [¶] (a) The means employed shall be such as to allow, to the extent practicable, eligible persons to secure health care in the same manner employed by the public generally, and without discrimination or segregation based purely on their economic disability."

Despite the above language supporting the generous intent of the Medicaid system, the government's provision of health services is not without limit. Subdivision (d) of 42 C.F.R. section 440.230 provides: "The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." A prior authorization system is one of the accepted "utilization control procedures" that can be employed as a limitation on the service provided to medical recipients.

Nevertheless, "a state's discretion in administering its Medicaid program does not shelter it from judicial action on those occasions where it has transgressed the strictures of the Social Security Act." (*Smith v. Miller* (7th Cir. 1981), 665 F.2d 172, 178.) In *Smith v. Miller*, the appellate court affirmed the district court in enjoining the Department of Public Aid in Illinois from failing to process applications for Medicaid within stipulated time limits and in ordering that, if they were not timely

processed, such applications would be automatically approved. The court observed "while a state's participation in the Medicaid program is purely voluntary and its acceptance of substantial federal funds uncoerced, once electing to participate, it must fully comply with federal statutes and regulations in its administration of the program. [Citations.]" (*Id.*, at p. 175.)

Similarly, in *Dodson v. Parham,* (N.D. Ga. 1977), 427 F.Supp. 97, a case involving reductions in pharmaceuticals to Medicaid patients, the court granted injunctive relief to Medicaid recipients and held that the cutbacks in the Georgia Medicaid program, taken together with a prior approval system that the court considered ineffective, is "medically unsound." (*Id.*, at p. 108.)

One of the elements of the prior approval system found inadequate by the United States District Court in Georgia was that a doctor of pharmacy rather than a physician made the decision in reviewing the prior approval. The court found it "unrealistic for defendants to presume that a doctor of pharmacy is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval for a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom he is intimately familiar. . . . [T]he decision must further reflect the practical experience only possessed by one who is skilled in the medical field and perhaps even in certain specialties." (*Id.*, at p. 108.) We find this logic persuasive and agree with amicus curiae that this flaw in the prior approval system invalidates the prior authorization procedures used by respondents herein.

Another flaw in respondents' prior authorization system involves the lack of a hearing prior to denial of the TARs. We do not agree with appellants that they were entitled to an evidentiary hearing prior to termination of any benefits. As stated in Welfare and Institutions Code section 10950, "*[n]otwithstanding any other provision of this code, there is no right to a state hearing when either (1) state or federal law requires automatic grant adjustments for classes of recipients unless the reason for an individual request is incorrect grant computation, or (2) the sole issue is a federal or state law requiring an automatic change in services or medical assistance which adversely affects some or all recipients.*" (Emphasis in original.) The initial cutback is indeed an across-the-board reduction in benefits mandated by state law and is not an individual denial thereof. Regarding the general cutback, therefore, while recognizing that health care is as important a benefit as other welfare issues (*Memorial Hospital v. Maricopa County* (1974), 415 U.S. 250), we do not believe that an evidentiary hearing prior to termination was mandatory under *Goldberg v. Kelly* (1970), 397 U.S. 254, 90 S.Ct. 1011, for those affected by only the across-the-board reduction.

We do, however, find that such hearing is necessary for those whose prior authorizations are denied after a TAR has been submitted. Such denials are based on individual factual grounds, not generalized criteria; and the person seeking medical assistance should be entitled to a hearing.

As stated in *King v. Woods* (1983), 144 Cal.App.3d 571, 576, "Welfare applicants and recipients are entitled to a prompt, fair hearing prior to the denial, termina-

tion or reduction of benefits. [Citations.]" The beneficiary of the entitlement is the person with a right to a prior hearing. (See *Paramount Convalescent Center, Inc. v. Department of Health Care Services* (1975), 15 Cal. 3d 489, 497, where our Supreme Court denied a pretermination hearing to a Medi-Cal provider and, in dicta, observed that the primary beneficiary is the person the cases have recognized has a right to a hearing; in accord, *Margulis v. Myers, supra,* 122 Cal.App.3d 335.)

Medi-Cal recipients were entitled to the named drugs before enactment of AB 799. Now they can obtain these same drugs only with prior authorization. Their predicament is at least as serious as those whose unemployment insurance benefits were terminated in *American Federation of Labor v. Employment Dev. Dept.* (1979), 88 Cal. App.3d 811, 821; Division Five of this Court held that those workers were entitled to a hearing. If the Department of Health intends to deny the TAR, the MedicCal recipient should be entitled to a pre-denial hearing.

Without the prior authorization procedures, many drugs that even respondents would consider "medically necessary" under the stricter present standards would be unavailable to those who need it. If the prior authorization procedure fails, the system would not be providing the assistance mandatory under the Social Security Act and must be enjoined.

Furthermore, even without flaws in the prior authorization procedures, federal regulations permit discrimination based on degree of medical necessity but not on the medical disorder for which the person suffers. (*White*

v. Beal supra, 555 F.2d at p. 1152.)[10] The Medi-Cal system, as limited by AB 799 and its regulations, does not comply with this requirement.

We do not doubt the good faith effort of the respondents to formulate a system that would be the least detrimental to Medical recipients. However, by making certain drugs totally unavailable, they ignored the necessity that some patients have for drugs that might be merely palliative for others. Infants and elderly people, for example, often suffer greatly from conditions that might be very minor in the rest of the population. Such decisions must most often be made on a patient-by-patient basis. Respondents have attempted to delete or require prior approval for drugs that often provide only minor relief of less serious conditions; their general rational basis, however, does not help the Medi-Cal recipient who, because of "medical necessity,"[11] requires the deleted medication.

The legal flaws in the current system compel a finding that appellants are likely to prevail at trial. The preliminary injunction must be expanded to include the prior approval system and must be extended in time.[12] Because

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[10] In *White v. Beal, supra,* the court affirmed disallowance of Pennsylvania's classification limiting expenditures for eyeglasses when needed for other than eye disease or pathology problems.

[11] We do not address the validity of the change in the standard of medical necessity since it is unnecessary to do in light of our resolution of the issues before us.

[12] At trial or before, respondents may be able to demonstrate that the procedures have changed to comply with the requirements stated above. On the other hand, appellants may be able to demonstrate that factually the procedures are far more egregious than they appeared to the court below.

of our resolution of these issues, it is unnecessary to address the other contentions raised by the parties.

The orders of the trial court are reversed. The case is remanded for further proceedings consistent with the views expressed herein.

CERTIFIED FOR PUBLICATION

/s/ Lui, J.

/s/ Danielson, J.

I concur in the judgment.

/s/ Klein, P.J.

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No. 84-1612

IN THE
SUPREME COURT
OF THE UNITED STATES
October Term, 1984

KENNETH W. KIZER, M.D., M.P.H., Director of the Department of Health Services; GEORGE DEUKMEJIAN, Governor of the State of California; STATE OF CALIFORNIA, a political entity,
Petitioners,

vs.

ANNA JENESKI, WILLIAM SWAIN, EDITH PANTILLA, and ARTHUR COLVIN,
Respondents.

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

COUNTERSTATEMENT OF QUESTIONS PRESENTED

Because this case is presented after a ruling granting respondents' request for preliminary injunctive relief, there are no issues which have been finally adjudicated by any court below which are now being presented to this Court.

Rather, the sole question presented to this Court is whether the California Court of Appeal properly found that respondents met their burden of demonstrating entitlement to preliminary injunctive relief, *i.e.*, (1) that pending trial the irreparable harm that respondents would suffer from denial of certain medications determined to be medically necessary by their treating physicians outweighs the expense petitioners will incur in providing such medications to indigents and medically needy, and (2) that there is a sufficient likelihood that respondents will prevail on the merits at trial.

The Court of Appeal's decision subsumes findings resolving the questions listed below, although these findings are not controlling on the ultimate issue of whether preliminary injunctive relief was properly granted since these questions relate only to the satisfaction of the second criteria for obtaining injunctive relief (*i.e.*, likelihood of success on the merits) and do not address numerous other substantive grounds[1] presented by respondents in support of

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[1] The Court of Appeals found it unnecessary to address the following issues raised by respondents and amicus in support of their motion, each of which constitutes an independent and adequate state or federal ground for concluding there is sufficient likelihood that respondents will prevail at trial:

1. The trial court erred in failing to maintain a preliminary injunction in effect since the regulation implementing the proposed cutbacks violates the "sufficiency requirement" of 42 C.F.R. §440.230(b).

2. The regulation implementing the proposed cutbacks violates the "simplicity of administration" and "best interest of the patient" requirements of 42 U.S.C. §1396(a)(19).

3. The subject regulation violates Title XIX of the Social Security Act's mandate of equality and therefore is invalid.

4. The subject regulation deprives Medi-Cal patients of the rights secured to them by 42 U.S.C. §1396(a)(19), in violation of the equal

their motion for preliminary injunction:

1. Whether implementation of legislatively mandated cutbacks in pharmaceutical services provided to Medi-Cal[2] recipients violates federal law by arbitrarily denying or reducing the amount, duration or scope of services to eligible recipients because of diagnosis, type of illness or condition;

2. Whether the prior authorization system (known as the "TAR" system), employed by the State of California as a utilization control of services provided to Medi-Cal recipients, is legally flawed because it does not provide for pre-denial hearings;

3. Whether the TAR system, as it applies to the prescription drug program, is legally flawed because it permits pharmacists to substitute their judgment for the medical judgment of the recipient's treating physician as to the medical necessity of prescribed drugs.

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protection clause of the Fourteenth Amendment.

5. The subject regulation is void and contrary to the law in that it discriminates against eligible Medi-Cal recipients based purely on economic disability.

6. Section 53(2) of AB 799 conferred upon the director of Health Services an unconstitutional delegation of power.

7. The subject regulation is an unconstitutional restraint on those Medi-Cal patients exercising their fundamental rights guaranteed by the California Constitution.

8. Petitioners' failure to consult the State Medical Advisory Committee as required by federal law requires invalidation of the drug formulary changes.

9. The prior approval system for certain pharmacy categories lacks the standards required by federal law.

Pet. App., pp. 9-11.

[2] Medi-Cal is the name given to the Medicaid program in California.

COUNTERSTATEMENT OF THE CASE

This case involves an action brought by Medi-Cal recipients to enjoin petitioners from implementing legislatively mandated cutbacks in pharmacy services provided by the Medi-Cal program. The implementing regulations (Title 22, Cal. Admin. Code §§ 59998-59999) eliminated six categories of drugs from the Medi-Cal program altogether, and put four other categories of drugs, which had previously been available on the Medi-Cal formulary without prior authorization, on a list for which prior authorization was required as a condition of Medi-Cal reimbursement.

Respondents moved for a preliminary injunction, raising 13 issues in support of their motion including, *inter alia*, that petitioners, through these cut-backs, had eliminated from the Medi-Cal program virtually all drugs necessary to treat particular classes of disorders, thereby reducing services to Medi-Cal recipients on the basis of diagnosis, illness or condition in violation of 42 C.F.R. §440.230(c).[3] As independent justification for injunctive relief, respondents argued that the prior authorization system (known as the "TAR" system) is legally flawed because it fails to offer pre-denial hearings to beneficiaries for whom TAR requests were denied, and further because it allows pharmacists to substitute their judgment for that of a beneficiary's treating physician as to whether a particular drug is medically

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[3] 42 C.F.R. §440.230(c) states as follows:

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration or scope of a *required service under §§440.210 and 440.220* to an otherwise eligible recipient solely because of the diagnosis, type of illness or condition. (Emphasis supplied.)

necessary to treat the beneficiary's illness.[4] Respondents contended that, by subjecting certain drugs to such prior authorization system, petitioners are improperly limiting or denying pharmacy services to Medi-Cal recipients.

The trial court denied respondents' motion for preliminary injunction, but the Court of Appeal reversed, ruling that the trial court abused its discretion in denying respondents' motion. Specifically, the Court of Appeal found that respondents satisfied both criteria for obtaining a preliminary injunction, *i.e.*, that the irreparable harm which Medi-Cal beneficiaries would suffer by denial of medically necessary drugs outweighed the harm petitioners would suffer through incurring the expense of such drugs, and that respondents demonstrated a sufficient likelihood of prevailing on the merits based upon the arguments described above. The Court of Appeal specifically noted that its decision *did not* constitute "an adjudication of the ultimate rights in controversy" as to the issues discussed above (Pet. App. A., p. 12). The court further stated that, because it agreed with respondents that the TAR system is legally invalid, it need not address the other issues raised by respondents in support of their motion for preliminary injunction (Pet. App. A., pp. 21-22).

SUMMARY OF ARGUMENT

Petitioners fail to present any grounds justifying the grant of certiorari in this case. Because the decision which petitioners ask this Court to review involves the granting of

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[4] Respondents presented nine additional independent and adequate state and federal grounds for relief which the Court of Appeal found it unnecessary to address. *See* footnote 1, *supra*.

a motion for preliminary injunction, where no final judgment on any issue has been rendered and where a vast number of issues remain undecided in any fashion, the relief which petitioners seek from this Court is premature and unwarranted.

Petitioners challenge the Court of Appeal's application of the rule of *White v. Beal*, 555 F.2d 1146 (3rd Cir. 1977), *i.e.*, that the non-discrimination provisions of 42 C.F.R. §440.230(c) apply equally to so-called optional and mandatory Medicaid services. Petitioners base this contention on a district court case which misinterprets the regulation in question and which, for that reason, is inconsistent with all other federal and state courts that have addressed the issue after *White v. Beal*.

In challenging the Court of Appeal's other findings, *i.e.*, that the prior authorization system is legally flawed by failing to provide pre-denial hearings and by allowing pharmacists to overrule physician decisions concerning medically necessary treatment, petitioners do not dispute the legal basis underlying the Court of Appeal's findings, but merely attempt to re-argue the evidence relating to these issues. In doing so, petitioners ignore many relevant facts, and grossly misstate others. Similarly, petitioners' assertion that TAR denials are neither arbitrary nor harmful to patients in need of the requested medication is totally contrary to the evidentiary record of this case.

ARGUMENT IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

A. The Issues Presented by This Case Are Not Appropriate for Review by Writ of Certiorari.

The principal issue presented by this case is whether the Court of Appeal properly found that respondents are entitled to preliminary injunctive relief until such time as a trial on the merits is held.[5] Petitioners do not assert, as a reason in support of their petition, that the Court of Appeal erroneously found that the irreparable harm suffered by respondents, who are denied medically necessary drugs, outweighs any harm suffered by petitioners in providing these medications to Medi-Cal beneficiaries. *See* Pet., p. 5, n. 6. The Court of Appeal cites with approval the following language from *Bass v. Richardson*, 338 F.Supp. 478, 489 (S.D.N.Y. 1971) as the basis of its finding:

> The State cannot prevail on the balance of incredible human suffering which the amendments to this program would create. The injury to those whose health is maintained on the slenderest chemical balance provided through medication is not merely irreparable; it is ultimate.

Pet. App., p. 14.

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[5] The Court of Appeal, in its opening discussion paragraph, acknowledges that the trial court's granting or denial of a preliminary injunction does not amount to an adjudication of the ultimate rights in controversy, but rather reflects a balancing of the respective equities of the parties in light of the probability of plaintiffs ultimately prevailing in the case. Pet. App. A., p. 12, quoting *Continental Baking Co. v. Katz*, 68 Cal.2d 512, 528 (1968).

Petitioners' failure to address the Court of Appeal's conclusion on irreparable harm is fatal to their request for relief from this Court, since this finding constitutes an independent and adequate state ground supporting the grant of injunctive relief. The law in California, as stated by the Court of Appeal, is that when considering a motion for preliminary injunction " 'in the last analysis the trial court must determine which party is more likely to be injured by the exercise of its discretion [citation] and it must then be exercised in favor of that party [citation].' " *Continental Baking Co. v. Katz*, 68 Cal.2d 512, 528 (1968). *See* Pet. App. A., p. 12. Because the Court of Appeal considered the balance of relative hardships to weigh so heavily in favor of respondents, it was clearly justified in granting the preliminary injunction if it found respondents made a reasonable showing that they were likely to succeed at trial. Unless petitioners can now establish that there is absolutely no basis on which it can be found that respondents have a reasonable likelihood of prevailing on the merits, petitioners cannot demonstrate to this Court that the preliminary injunction was erroneously granted.

Petitioners do not, however, undertake the task of arguing that there was no basis justifying the preliminary injunctive relief granted to respondents. Instead, petitioners challenge only the Court of Appeal's findings on three of the available bases for ruling in respondents' favor.[6] Petitioners' arguments do not, therefore, resolve the ultimate question of whether respondents are entitled to a preliminary injunction.

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[6] Petitioners totally ignore the remaining nine independent and adequate grounds asserted in support of respondents' motion for injunctive relief. *See* footnote 1, *supra*.

Moreover, assuming *arguendo* that petitioners had successfully undertaken to establish that there was no basis for concluding that there is a reasonable likelihood that respondents will succeed on the trial in this action, it does not follow that the Court of Appeal's decision to grant respondents' motion for a preliminary injunction was erroneous. "[T]he possibility that the party obtaining a preliminary injunction may not win on the merits at the trial is not determinative of the propriety or validity of the trial court's granting the preliminary injunction." *B.W. Photo Utilities v. Republic Molding Corporation*, 280 F.2d 806, 807 (9th Cir. 1960). As discussed above, the court's assessment of the probability that the moving party will ultimately succeed is only one criteria considered in ruling on a motion for preliminary injunction. Indeed, it is the fact that the court has such broad discretion to consider numerous factors in deciding whether to grant or deny a preliminary injunction that makes its determination on this question inappropriate for review by this Court.

In addition, it is respectfully submitted that the reasons advanced by petitioners in support of their petition are not of a character which this Court will consider in the exercise of its discretion. *See* Rules of the Supreme Court of the United States, Rule 17. Specifically, petitioners do not contend that the Court of Appeal decided a federal question in a way in conflict with another state or federal appellate court, nor that this case involves any novel or important question of law which requires clarification by this Court.

Rather, the arguments raised by petitioners deal largely with pragmatics and fiscal concerns and, therefore, belong more properly with the California Legislature which can weigh the various options, information and social issues that exist in the area of providing health care to indigents. As to

the Court of Appeal's specific findings, they are all fully supported by and consistent with each federal and state appellate court which has considered the issues discussed by the Court of Appeal.

For these reasons, it is respectfully submitted that review by this Court of the Court of Appeal's decision is improper. In addition, for the reasons set forth below, it is respectfully submitted that the Court of Appeal properly decided the questions of law addressed in its opinion.

Following is a rebuttal to the three arguments raised by petitioners which, again, respondents contend cannot be dispositive of the issue of whether respondents are entitled to injunctive relief.

B. The Court of Appeal Is Correct in Its Finding that 42 C.F.R. §440.230(c) Applies to Changes in Medi-Cal's Prescription Drug Program.

Petitioners' primary argument in support of their petition is that the Court of Appeal erred in finding that 42 C.F.R. §440.230(c), which prohibits reductions in "required [Medicaid] services" on the basis of diagnosis or illness, applies to the prescription drug component of the Medi-Cal Program, a so-called "optional" Medi-Cal service.[7] Petitioners further make the unsubstantiated assertion that this particular finding of the Court of Appeal, if not reviewed

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[7] Petitioners' assertion (Pet., p. 11) that "Petitioners were successful in convincing the trial court that federal regulation [42 C.F.R. §440.230(c)] had no applicability to an optional service such as the prescription drug program" is incorrect. The trial court made no express finding whatsoever on the applicability of 42 C.F.R. §440.230(c) to the prescription drug program or the cutbacks in question.

by this Court, will encourage legislatures throughout the nation to discontinue the prescription drug component in its entirety. Pet., p. 16.

Petitioners are wrong on both counts. With respect to their analysis of the scope of 42 C.F.R. §440.230(c), petitioners' argument that *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977) is no longer good law due to changes in the regulation it interprets is ill-founded. A comparison of current 42 C.F.R. §440.230(c) to its predecessor shows that the changes in question, *i.e.*, the substitution of the phrase "required services for the categorically needy and the medically needy," was strictly cosmetic.[8] 42 C.F.R. §§440.210 and .220 are titled respectively "Required Services for the Medically Needy," and the services which are "required" for the "categorically needy" and the "medically needy" are virtually unchanged today from the time *White v. Beal* was decided.[9] Thus, the rule of *White v.*

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[8] According to the opinion of the *White* court, the predecessor to 42 C.F.R. §440.230(c), former 45 C.F.R. §249.10(a)(5)(i), provided in pertinent part as follows:

With respect to the *required services for the categorically needy... and the medically needy...* the State may not arbitrarily deny or reduce the amount, duration, or scope of, such services to an otherwise eligible individual solely because of the diagnosis, type or illness of condition. *White v. Beal, supra*, 555 F.2d at 1151.

[9] 42 C.F.R. §440.210, entitled "Required Services for the Categorically Needy," provides as follows:

A state plan must specify that, as a minimum, categorically needy recipients are provided the services as specified in §§440.10 through 440.50, 440.70, and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165.

42 C.F.R. §440.220, entitled "Required Services for the Medically Needy," provides in pertinent part as follows:

A state plan that includes the medically needy must specify that the medically needy are provided, as a minimum, the following services...

Beal remains applicable today.

Indeed, with only one known exception, the federal and state courts interpreting 42 C.F.R. §440.230(c) have shown no hesitation in following the rule of *White v. Beal* after the amendment of the regulation. *See Simpson v. Wilson*, 480 F.Supp. 97, 102 (D.Vt. 1979) (42 C.F.R. §440.230(c) applied to "optional" eyeglass component of Vermont Medicaid plan); *Hodgson v. Bd. of County Com'rs, County of Hennepin*, 614 F.2d 601, 608 (8th Cir. 1980) ("Once a state designates services it will subsidize, it may distinguish between eligible and ineligible recipients *only* on the basis of their degree of medical necessity"); *see also Helen Vander Steen v. Dept. of Health and Social Services of the State of Wisconsin*, No. 84-047, Ct. of App. of Wisconsin (1984), Slip Limited Precedent Opinion at p. 3 (attached hereto as Appendix A) (42 C.F.R §440.230(c) applied to "optional" intermediate care facilities component of Wisconsin Medicaid plan), which states:

(d)...

(1) The services contained in §§440.10 through 440.50 and (to the extent nurse-midwives are authorized to practice under State law or regulation) 440.165; or

(2) The services contined in any seven of the sections in §§440.10 through 440.165.

At the time of *White v. Beal*, required services for the categorically needy included at least the first five items set forth in 42 U.S.C. § 1396d(a), and required services for the medically needy included at least the first five items or any seven of the sixteen items set forth in 42 U.S.C. § 1396d(a). *White v. Beal, supra*, 444 F.2d at 1152, n.6. These sixteen items are additionally listed as 42 C.F.R. §§440.210 through .165, and a review of 42 C.F.R. §§440.210 and .220, set forth above, show that they require the same minimum services to be provided the categorically and medically needy respectively as at the time of *White v. Beal*.

> Intermediate care facilities are a required service. While such services do not form part of a state Medicaid plan's mandatory nucleus for the categorically needy, 42 U.S.C. § 1396a(1)(10)(4) [sic] (1983), such services are required by the Wisconsin plan....In *White v. Beal*, 555 F.2d 1146 (3d Cir. 1977), the regulation was similarly applied to a service required by the Pennsylvania plan that was not specifically mandated by the federal statute. Moreover, intermediate care facilities are also required for the medically indigent [under the Wisconsin plan], and federal law precludes giving less generous aid to the categorically needy than to the medically needy. *Sinclair v. Dept. of Health and Social Services*, 77 Wis.2d 322, 334, 253 N.W.2d 245, 250 (1977); 42 U.S.C. § 1396a(a)(10)(B) (1983).

The only case to not follow *White v. Beal* is *Ledet v. Fischer*, 548 F.Supp. 775 (M.D.La. 1982), the district court case upon which petitioners rely. However, a review of *Ledet* indicates that the court's interpretation of the meaning of "required services" under 42 C.F.R § 440.230(c) is patently erroneous. Specifically, the court in *Ledet* mistakenly interpreted "required service" simply and solely by reference to the services which must be provided to categorically needy under 42 C.F.R. § 440.210, failing to include or accord any significance to the services required to be provided the medically needy under 42 C.F.R. § 440.220. *See Ledet v. Fischer, supra*, 548 F.Supp. at 786.[10]

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[10] Petitioners repeat this same reasoning error in their petition. *See* Pet., p. 12, n. 9. After first itemizing those minimum services which are required for the categorically needy under 42 C.F.R. § 440.210, petitioners dismiss 42 C.F.R. § 440.220 by stating that it "similarly does

Such an analysis is grossly mistaken for, by its very failure to specify any particular service which must be provided to the medically needy, 42 C.F.R. §440.220 necessarily denotes each and every service actually offered to the medically needy, whether mandatory or optional for the categorically needy, to be a "required service for the medically needy." Were it otherwise, no service under 42 C.F.R. §440.220 could ever be a "required" one, even though the regulation is titled "Required Services for the Medically Needy." Further, the reference in 42 C.F.R. §440.230(c) to 42 C.F.R. §440.220 would be superfluous. As a cardinal rule of statutory interpretation, statutes must be interpreted so as to give meaning to every phrase and word therein.

It is this simple logic that underlies the *White* decision, and which has no doubt additionally guided the Court of Appeal in reaching its finding.[11] Petitioners' analysis, mistaking the significance of a cosmetic amendment and failing as it does to take into account key provisions of the regulatory language it purports to explain, is simply wrong.

The second prong of petitioners' argument, *i.e.*, that legislatures will be encouraged to eliminate the prescription drug program in its entirety on accouant of the Court of Appeal decision, is both irrelevant speculation and meritless. As a practical matter, legislatures are well aware that medications are cost-effective, that reductions in Medicaid medication benefits to ill persons who cannot afford to purchase medications on their own will result in

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not include the requirement that prescription drug services be provided."

[11] Petitioners do not contest the fact that the California Medi-Cal Program provides prescription drug services as a benefit to medically needy beneficiaries pursuant to 42 C.F.R. §440.220.

worsening of their conditions, increased physician visits, and hospitalization, and thus increased program costs. Therefore, there is no reason to suppose that legislatures will eliminate pharmacy services altogether from their respective Medicaid programs, and consequently risk enormous cost increases, in order to avoid providing certain medications to beneficiaries.

Indeed, it is clear that the California Legislature, at the time it mandated cutbacks in Medi-Cal pharmacy services, was well aware of its social responsibility to prevent human suffering and of the economic benefit afforded by providing medications to Medi-Cal beneficiaries. Given the fiscal problems which existed in 1982, the Legislature could have eliminated the drug component of the Medi-Cal program at that time. Instead, the Legislature directed the Department of Health Services ("Department") to eliminate primarily those drugs which provided only minor symptomatic relief. Unfortunately the Department violated the law in attempting to do so for, contrary to the prohibition of 42 C.F.R. §440.230(c), it eliminated medications on the basis of diagnosis and illness, making it impossible for physicians to treat certain illnesses and conditions which, if untreated, could cause extreme suffering, serious illnesses and even death among Medi-Cal patients.

C. The Court of Appeal Is Correct in Its Finding that Medi-Cal Beneficiaries Are Entitled to Pre-Denial Hearings With Respect to TARs for Affected Prescription Drugs.

Petioners' second argument, *i.e.*, that the Court of Appeal erred in finding that the TAR system is legally flawed because of its failure to provide pre-denial hearings to

Medi-Cal recipients, is equally unpersuasive. Despite petitioners' lengthy discussion (Pet., pp. 17-25), the simple truth is that the Court of Appeal's finding that a pre-denial hearing is required is well-founded as both a legal and factual matter. As a legal matter, the finding finds overwhelming support in the various California and federal cases cited by the Court of Appeal (*see* Pet. App. A, pp. 19-20), particularly the recent California decisions in *American Federation of Labor v. Employment Dev. Dept.*, 88 Cal.App.3d 811 (1979) and *King v. Woods*, 144 Cal.App.3d 571, 576 (1983). As a factual matter, the finding finds similarly solid support in the evidence contained in the record on appeal, particularly the various declarations submitted to the trial court by plaintiffs in both the *Jeneski* and companion *Fabach* actions.

Significantly, petitioners make no attempt to distinguish away the supporting cases cited by the Court of Appeal, but essentially limit their objection to the Court of Appeal's factual determination. *See* Pet., pp. 20-24. In doing so, however, petitioners misstate and distort the evidentiary record of this case. Most egregious of these misstatements is petitioners' assertion that most of the drugs made subject to prior authorization have equivalents on the Medi-Cal formulary (available without prior authorization) or are readily and cheaply available over-the-counter. *See* Pet., pp. 21-22. The entire basis of the *Jeneski* lawsuit, and a fact that is singularly well-established by the evidentiary record, is that formulary equivalents and inexpensive over-the-counte substitutes are *not* available to Medi-Cal beneficiaries for whom TARs are denied.

Similarly, petitioners' assertion that there is little risk of erroneous and non-arbitrary TAR denials (*see* Pet., pp. 22-23) is wholly contradictory to the overwhelming evidence

submitted both in the *Jeneski* and *Fabach* actions which, as noted by the Court of Appeal (Pet. App. A., p. 7), demonstrated that the overwhelming percentage of TARs for affected drugs were rejected and that such rejections were based upon reasons and criteria that varied depending on the particular Medi-Cal consultant reviewing the TAR.

Finally, petitioners' prediction that the State will face an overwhelming new burden should pre-denial hearings be required (Pet., pp. 23-24) is not only highly speculative, but highly unlikely if, as petitioners represent, an extensive post-denial hearing system is already in place. Surely a mere shift in the timing of the hearing process from post- to pre-denial should make little, is any, difference on the burden the hearing system places on the State.[12]

D. The Court of Appeal Is Correct in Its Finding that the TAR System Is Flawed Since Pharmacists, Instead of Physicians, Make the Ultimate Determinations Concerning Drug Treatment Which Is Medically Necessary for a Patient.

As its final point, petitioners contend that the Court of Appeal erred in its finding that the prior approval process is flawed due to its failure to provide for the review of TAR requests by physicians. *See* Pet., pp. 25-27. In finding the system flawed in this respect, the Court of Appeal reasoned as follows:

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[12] Petitioners' additional argument that the Court of Appeal failed to acknowledge existing *post*-denial appeal procedures is, of course, a matter wholly irrelevant to the proprietary of the Court of Appeal's finding as to the need for *pre*-denial hearing procedures.

> Similarly, in *Dodson v. Parham*, (N.D. Ga. 1977) 427 F.Supp. 97, a case involving reductions in pharmaceuticals to Medicaid patients, the court granted injunctive relief to Medicaid recipients and held that the cutbacks in the Georgia Medicaid program, taken together with a prior approval system that the court considered ineffective, is "medically unsound." (*Id.*, at p. 108.)
>
> One of the elements of the prior approval system found inadequate by the United States District Court in Georgia was that a doctor of pharmacy rather than a physician made the decision in reviewing the prior approval. The court found it "unrealistic for defendants to presume that a doctor of pharmacy is capable of making that type of informed judgment which is necessary to ultimately review any request for prior approval for a drug which the requesting physician in his experience has found to be medically necessary and indicated for a patient with whom is is ultimately familiar. ...[T]he decision must further reflect the practical experience only possessed by one who is skilled in the medical field and perhaps even in certain specialties." (*Id.*, at p. 108.) We find this logic persuasive and agree with amicus curiae that this flaw in the prior approval system invalidates the prior authorization procedures used by [petitioners] herein.

Pet. App. A, p. 18.

Petitioners' complaint that the Court of Appeal cited only the *Dodson* case as authority (*see* Pet., p. 25) for its finding is, of course, irrelevant. The *Dodson* case is good

law, and petitioners acknowledge the truth of the premise of the *Dodson* holding, *i.e.*, that Congress has emphasized physician discretion in the treatment of Medicaid patients. *See* Pet., p. 26.

Petitioners' attempt to distinguish away the *Dodson* case on the grounds that *Dodson* failed to indicate whether certain factors present in the California prior authorization system also existed in the Georgia prior authorization system (*see* Pet., pp. 25-26) is equally unavailing. The *Dodson* court's failure to specify that such factors existed in the Georgia program hardly indicates that they did *not* exist in that program. In any event, the evidence in this case demonstrates overwhelmingly that, despite the presence of the factors in question, *i.e.*, the availability of medical consultants and the existence of specific criteria for reviewing TARs, the decisions rendered by Medi-Cal's pharmacist TAR reviewers were remarkably inconsistent and lackiang in medical soundness.

Finally, petitioners' attempt to characterize the decisions of the pharmacist TAR reviewers as simply ministerial determinations which do not interfere with a physician's choice of proper medical treatment for his patients is disingenuous and utterly improper. Most egregious is the following statement, found on pages 26-27 of the petition:

> Department pharmacists, in ruling on TARs, are not second guessing the treating physician but are merely ensuring that the prescribed drug is reimbursable under the statutory and regulatory limitations which the Legislature and the Department have enacted and promulgated.

What petitioners neglect to point out is that the pharmacist measures the request against a "medically necessary" or "necessary to prevent significant disability or

death" standard for approval. If the physician can satisfy the pharmacist that the proposed drug therapy meets such a requirement then the medication is approved; if he cannot persuade the pharmacist, then the medication is denied.

Clearly, as Congress has mandated, and as the *Dodson* court and the Court of Appeal have found, when a person's health and life are at stake, decisions regarding medical treatment should be delegated to the patient's physician, not a pharmacist employed by a state bureaucracy.

CONCLUSION

This case presents neither a novel question of federal law, nor one which has been decided in conflict with other federal or state appellate courts. Rather, the decision of the Court of Appeal here at issue involves a finding that, on balance, respondents are entitled to preliminary injunctive relief. Moreover, the Court of Appeal's decision is in all respects correct, and is consistent with and fully supported by the decisions of the state and federal appellate courts which have addressed the federal questions presented by this case.

It is respectfully submitted that the Petition for Writ of Certiorari should be denied.

Respectfully submitted,

MARKS AND STEVENSON
RONALD S. MARKS

JONATHAN WEXLER

APPENDIX A

HELEN VANDER STEEN, Petitioner-Respondent, v. DEPARTMENT OF HEALTH AND SOCIAL SERVICES OF THE STATE OF WISCONSIN, Appellant.

NO. 84-047

UNPUBLISHED LIMITED PRECEDENT OPINION

Court of Appeals of Wisconsin
District III

Slip Opinion

November 6, 1984

APPEAL from an order of the circuit court for Brown county: VIVI L. DILWEG, Judge. Affirmed.

Before Foley, P.J., Dean and Cane, JJ.

DEAN, J. The Department of Health and Social Services appeals an order to reinstate medical assistance benefits under secs. 49.43 to 49.497, Stats. The department determined that Helena Vander Steen was ineligible for reimbursement of inpatient nursing care pursuant to sec. 49.45(6m) (i), Stats. The trial court ordered reinstatement on the grounds that the department relied on an improperly promulgated rule in depriving Vander Steen of benefits and that sec. 49.45(6m) (i) violated federally mandated "comparability" requirements. 42 U.S.C. § 1396a(a) (10) (B) (1983). Because we conclude that the statute conflicts with regulations promulgated under the Medicaid Act, Title

XIX of the Social Security Act of 1965, 42 U.S.C. §§ 1396-1396i (1983), we affirm.[1]

Vander Steen entered an intermediate care facility on December 3, 1982. As a Supplemental Security Income recipient under federal Title XVI, she was eligible for Medicaid assistance as a categorically needy person. Section 49.46(1) (a) 4, Stats. Intermediate care facility services are an available Medicaid benefit, sec. 49.46(2) (b) 6a, Stats., and Vander Steen received assistance because she was admitted for ICF-1 care, sec. 49.45(6m) (i) 1, Stats. In March, 1983, the department reduced her level of care to ICF-3. Section 49.45(6m) (i) 2, Stats., limits reimbursement of ICF-3 nursing care to those persons who entered a facility before October 1, 1981, or who have a primary diagnosis of developmental disability or chronic mental illness if they entered a facility on or before November 1, 1983. Vander Steen satisfied the November 1, 1983, cutoff. The department, however, concluded that her diagnosis of senility was not within the statutory exceptions permitting reimbursement. Although the ICF-3 level of care includes individuals who are mentally handicapped, disabled from aging, or chronically ill, Wis. Admin. Code §HSS 132.13(13) (a) (1982), reimbursement is limited to the developmentally disabled and the chronically mentally ill. The question is whether this limited exception complies with federal law.

In reviewing a circuit court order reversing a department order, our scope of review is identical to that of the circuit

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[1] Because we conclude that §49.45(6m) (i), Stats., conflicts with the federal law, we do not consider the argument that a department memorandum interpreting the statute is an administrative rule under §227.01(9), Stats., which was not promulgated in accordance with the Administrative Procedure Act.

court. *Boynton Cab Co. v. DILHR*, 96 Wis.2d 396, 405, 291 N.W.2d 850, 855 (1980). Since the issue in this case involves the interpretation and application of federal law, we do not accord the department any deference. *Swanson v. Department of Health and Social Services*, 105 Wis.2d 78, 82-83, 312 N.W.2d 833, 835 (Ct. App. 1981).

Once a state accepts federal Medicaid funds, it must abide by the federal law's purposes and provisions. *Rickaby v. Wisconsin Department of Health and Social Services*, 98 Wis.2d 456, 457, 297 N.W.2d 36, 37 (Ct. App. 1980). Controlling federal law includes the requirements imposed by both the federal statutes and the regulations of the Secretary of Health and Human Services. *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981). One regulation details the permissible and impermissible ways in which a state may exclude or diminish payment for certain services. A state may distinguish between eligible and ineligible recipients of a provided service on the basis of medical need. *Hodgson v. Board of County Commissioners*, 614 F.2d 601, 608 (8th Cir. 1980); 42 C.F.R. §440.230(d) (1983). A Medicaid agency, however, may not arbitrarily deny or reduce a required service's amount, duration, or scope to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition. 42 C.F.R. §440.230(c) (1983).

Section 49.45(6m) (i) denies service solely on the basis of diagnosis. The statute refers specifically to diagnosis as the distinguishing characteristic. There is no indication that the state considered the medical need of the developmentally disabled and the chronically mentally ill under ICF-3 care to be greater than the medical need of patients like Vander Steen. Their need for the same level of care is evidence exactly to the contrary. The department treated Vander Steen differently solely because she suffers from infirmities

of aging rather than developmental disabilities or chronic mental illness. The department's action is improper under the federal regulation.

Intermediate care facility services are a required service. While such services do not form part of a state Medicaid plan's mandatory nucleus for the categorically needy, 42 U.S.C. § 1396a(1) (10) (4) (1983), such services are required by the Wisconsin plan, sec. 49.46(2) (b)6a, Stats. In *White v. 5 5 Beal*, 555 F.2d 1146 (3d Cir. 1977), the regulation was similarly applied to a service required by the Pennsylvania plan that was not specifically mandated by the federal statute. Moreover, intermediate care facilaity services are also required for the medically indigent, sec. 49.47(6) (a), Stats., and federal law required for the medically indigent, sec. 49.47 (6) (a), Stats., and federal law precludes giving less generous aid to the categorically needy than to the medically needy. *Sinclair v. Department of Health and Social Services*, 77 Wis.2d 322, 334, 253 N.W.2d 245, 250 (1977); 42 U.S.C. § 1396a(a) (10) (B) (1983).

There is no argument that Vander Steen is not an otherwise eligible Medicaid recipient. The circuit court, therefore, correctly reversed the department's order and required reinstatement of Vander Steen's medical assistance. While the statute now mandates equal treatment of ICF-3 patients who enter a facility after November 1, 1983, the department cannot discriminate between patients who entered a facility on or before November 1, 1983, solely on the basis of diagnosis.

By the Court. — Order affirmed.

Not recommended for publication in the official reports.

DISPOSITION:

By the Court. — Order affirmed.

Not recommended for publication in the official reports.